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APPLICATION NO.	FILI	NG DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/776,599	02/01/2001		Kenneth F. Buechler	071949-2404	9314	
7.	590	10/31/2002				
Michael A. W			EXAMINER			
FOLEY & LAI 23rd Floor	RDNER			EPPERSO	EPPERSON, JON D	
402 W. Broadway					·	
San Diego, CA 92101				ART UNIT	PAPER NUMBER	
•				1639	<del>-</del>	
				DATE MAILED: 10/31/2002	- <u></u>	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
•	09/776,599	BUECHLER ET AL.				
Office Action Summary	Examiner	Art Unit				
1-le Cons	Jon D Epperson	1639				
The MAILING PATE of this communication app Period for Reply	pears on the cover sheet w	vith the correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
1) Responsive to communication(s) filed on						
l	is action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims						
4)⊠ Claim(s) <u>30-46</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.		,				
8)⊠ Claim(s) <u>30-46</u> are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examiner						
10)☐ The drawing(s) filed on is/are: a)☐ accept						
Applicant may not request that any objection to the	drawing(s) be held in abeya	ance. See 37 CFR 1.85(a).				
11) The proposed drawing correction filed on		lisapproved by the Examiner.				
If approved, corrected drawings are required in rep						
12)☐ The oath or declaration is objected to by the Exa	ıminer.					
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) ☐ The translation of the foreign language provisional application has been received.  15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	4) Interview S 5) Notice of Ir 6) Other:	Summary (PTO-413) Paper No(s)  nformal Patent Application (PTO-152)				

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## **DETAILED ACTION**

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Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The fax number is (703) 308-4315. A fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Andrew Wang, Supervisory Patent Examiner, at (703) 306-3217. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Please note: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1639. Please also note the change in Examiner.

1. Upon further review of applicant's added claims, an additional restriction and/or election was deemed necessary as outlined below.

#### Election/Restriction

- 2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 30-42 and 45-46, drawn to a product described as a "fluorescent particle", classified variously in class 252, subclass 301.16, class 540, subclass 122.
  - II. Claim 43, drawn to a product described as a fluorescent particle that "further comprises an antibody", classified variously in class 424, subclass 178.1+; class 424, subclass 130.1+; class 530, subclass 387.1+; class 252, subclass 301.16; class 540, subclass 122.
  - III. Claim 44, drawn to a product described as a fluorescent particle that "further comprises a nucleic acid", classified variously in class 536, subclass 23.1; class 252, subclass 301.16; class 540, subclass 122.

- 3. The inventions are distinct, each from the other because of the following reasons:
- 4. Groups I-III represent patentably distinct products. Groups I-III represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. For example, Group III is drawn to a fluorescent particle that "further comprises a nucleic acid", which requires different reagents and/or materials than Groups I and II (i.e., requires a nucleic acid). Likewise, Group II is drawn to a fluorescent particle that "further comprises an antibody", which requires different reagents and/or materials than Groups I and III (i.e., requires an antibody). Therefore, art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Consequently, Groups I-III have different issues regarding patentability and enablement and represent patentably distinct subject matter.
- 5. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

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6. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-IV. Election is required as follows.

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7. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species. Claim 30 is generic.

# Subgroup 1: Species of fluorescent particle (see claim 30)

Applicant must elect, for the purposes of search, a <u>single species</u> corresponding to a "fluorescent particle" wherein a <u>specific structure</u> is set forth, which clearly shows <u>all of the atoms and bonds</u> that are necessary to define the "fluorescent particle" including the "first compound" and the "second compound" and the "particle" itself including all points of attachment. Applicant should <u>not</u> use notations like X or R when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected. Furthermore, applicant must indicate what the "particle" is made out of i.e., latex or silica (see claims 31 and 32) and must also indicate the size of the particle (see claims 45 and 46). Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read <u>only</u> on the single elected species of subgroup 1.

8. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species. Claim 43 is generic.

# Subgroup 1: Species of fluorescent particle (see claims 30 and 43)

Applicant must elect, for the purposes of search, a <u>single species</u> corresponding to a "fluorescent particle" wherein a <u>specific structure</u> is set forth, which clearly shows <u>all of the atoms and bonds</u> that are necessary to define the "fluorescent particle" including the "first compound" and the "second compound" and the "particle" itself including all points of attachment. Applicant should <u>not</u> use notations like X or R when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected. Furthermore, applicant must indicate what the "particle" is made out of i.e., latex or silica (see claims 31 and 32) and must also indicate the size of the particle (see claims 45 and 46). Furthermore,

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applicant must indicate which claims read on the elected species i.e., which claims read only on the single elected species of subgroup 1.

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Subgroup 2: Species of antibody (see claim 43)

Applicant must elect, for the purposes of search, a <u>single species</u> of antibody. Furthermore, applicant <u>must</u> indicate which claims read on the elected species i.e., which claims read <u>only</u> on the elected species of subgroup 2.

9. If applicant elects the invention of Group III, applicant is required to elect from the following patentably distinct species. Claim 44 is generic.

# Subgroup 1: Species of fluorescent particle (see claims 30 and 44)

Applicant must elect, for the purposes of search, a <u>single species</u> corresponding to a "fluorescent particle" wherein a <u>specific structure</u> is set forth, which clearly shows <u>all of the atoms and bonds</u> that are necessary to define the "fluorescent particle" including the "first compound" and the "second compound" and the "particle" itself including all points of attachment. Applicant should <u>not</u> use notations like X or R when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected. Furthermore, applicant must indicate what the "particle" is made out of i.e., latex or silica (see claims 31 and 32) and must also indicate the size of the particle (see claims 45 and 46). Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read <u>only</u> on the single elected species of subgroup 1.

## Subgroup 2: Species of nucleic acid (see claim 44)

Applicant must elect, for the purposes of search, a <u>single species</u> of nucleic acid. Furthermore, applicant <u>must</u> indicate which claims read on the elected species i.e., which claims read <u>only</u> on the elected species of subgroup 2.

10. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have

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different issues regarding patentability and represent patentably distinct subject matter.

Therefore, this does create an undue search burden, and election for examination purposes as

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indicated is proper.

held to be allowable.

11. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally

- 12. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a a rejection under 35 U.S.C. 103(a) of the other invention.
- 13. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
- 14. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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- 15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.
- Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 17. Applicant is also reminded that a 1 month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

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## Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D. October 29, 2002

BENNETT CELSA